

## REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1-8 and 11-28 are pending. The amendment is fully supported by the original disclosure and, thus, no new matter is added by their entry. Support for the “connector” device may be found throughout the disclosure (e.g., page 1, line 9; page 3, line 1; page 3, line 10; and page 3, line 24, of the specification). The device disclosed in the present application is a connector that fits and removes to a first catheter. It connects the first catheter to other two catheters in a two-way connection.

### *35 U.S.C. 103 – Nonobviousness*

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *In re Kahn*, 78 USPQ2d 1329, 1334 (Fed. Cir. 2006) citing *Graham v. John Deere*, 148 USPQ 459 (1966). The *Graham* analysis needs to be made explicitly. *KSR v. Teleflex*, 82 USPQ2d 1385, 1396 (2007). It requires findings of fact and a rational basis for combining the prior art disclosures to produce the claimed invention. See *id.* (“Often, it will be necessary for a court to look to interrelated teachings of multiple patents . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue”). The use of hindsight reasoning is impermissible. See *id.* at 1397 (“A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning”). Thus, a prima facie case under Section 103(a) requires “some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct.” *Kahn* at 1335; see *KSR* at 1396. An inquiry is required as to “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* at 1396. But a claim that is directed to a combination of prior art elements “is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.*

Finally, a determination of prima facie obviousness requires a reasonable expectation of success. See *In re Rinehart*, 189 USPQ 143, 148 (C.C.P.A. 1976).

Applicant's claim 1 requires that their device include a connection extending from the device's container with a connector comprising a sleeve and a spring. The sleeve moves a tubular element's end toward and away from recesses (housing) containing a closing means, which is provided with a pointed end. Movement of the tubular element's end results in fitting and removing of the closing means with respect to other catheters.

1. Claims 1-8, 11-20, 25-26 and 28 were rejected under Section 103(a) as allegedly unpatentable over Littman (U.S. Patent 3,157,201) in view of Diaz et al. (U.S. Patent 5,693,021) or Fujii (U.S. Patent 6,485,483). Applicant traverses.

In the claimed device, a connector comprising a movable sleeve and a spring that applies a force opposite to movement of the sleeve is used to displace a tubular element. Movement of the tubular element is used to engage the end thereof with the pointed end of a closing means (i.e., plug).

In contrast, Fig. 5 of Littman shows that two closing means are present, acting as shutters in respective one-way valve arrangements, wherein there is *no* movement of the tubular member encasing the shutters of a device. A spring causes a shutter to close its respective passageway unless an external pressure is applied to the external face of the shutter (i.e., conventional operation of any spring-operated one-way valve).

To compensate for this deficiency of Littman, the Examiner alleged that pressure may be exerted to move the shutters using a syringe device. Diaz discloses a syringe with a plunger working in opposition to the force of a spring encased inside a sleeve. The Examiner's concluded that Diaz's device may be used to exert a pressure that causes Littman's shutters to open and close. But this combination would not be considered to have a reasonable expectation of success by one of ordinary skill in the art, for at least two reasons.

First, such a combination would prevent Littman's one-way valves from working. A proposed modification of a cited disclosure *cannot* render it unsatisfactory for its intended purpose. See M.P.E.P. § 2143.01 at 2100-140. Here, the Examiner's proposal does not support a finding of prima facie obviousness because his combination as

described in the Office Action would render Littman's one-way valves unsatisfactory for their intended purpose. Therefore, the combination of Littman and Diaz would not make Applicant's claimed invention obvious.

Second, Applicant's claimed combination of sleeve and spring, which moves a tubular end to have it engage with the pointed end of a plug, would not result from the combination of Littman and Diaz with a reasonable expectation of success. In fact, Diaz's syringe may open and close Littman's one-way valves without moving the end of the tubular end to be engaged and causing the simultaneous passage of a fluid at the valve aperture. Here, the Examiner's proposal does not support a finding of prima facie obviousness because his combination would not result in Applicant's claimed invention.

Alternatively, to compensate for Littman's deficiency, the Examiner alleged that a sleeve-and-spring arrangement can be used to open the terminal end of a catheter by pushing the end outside the sleeve itself. Fuji discloses a component in Fig. 16 that is a terminal end of a catheter 10 that is closed by plug 12. Movement causes the plug to be released into a receiving recess *only*. But it was neither taught nor obvious that there is engagement between tubular end of a catheter and pointed end of a closing means (i.e., plug). Therefore, the combination of Littman and Fujii would not make Applicant's claimed invention obvious.

2. Claims 1-3, 7-8, 11-20, 25-26 and 28 were rejected under Section 103(a) as allegedly unpatentable over Fuson et al. (U.S. Patent 3,957,082) in view of Diaz et al. (U.S. Patent 5,693,021). Applicant traverses. His invention in accordance with claim 1 is described in two paragraphs on the preceding page.

Fuson shows a simple three-way valve with four connection tubes. They may be closed by their respective caps 80. After the tube's end is unplugged, a catheter may be joined thereto by screwing a threaded fitting at the catheter terminal. The Examiner alleged Diaz discloses a syringe that may be coupled to the connection tubes. But such a combination does not apply a pressure to a plug (which is *not* mentioned in either Fuson or Diaz) to close the catheter fitting. It also appears that the devices of Fuson and Diaz could not be combined to produce a useful technical effect. Therefore, Applicant's claimed combination of sleeve and spring, which moves a tubular end to have it

engage with the pointed end of a plug, would not result from the combination of Fuson and Diaz with a reasonable expectation of success.

3. Claims 21-24 were rejected under Section 103(a) as allegedly unpatentable over Littman in view of Diaz/Fujii or Fusion in view of Diaz (either of the previous rejections), and further in view of Folden (U.S. Patent 5,336,173). Applicant traverses because the additional citation of Folden does not correct the deficiencies discussed above with respect to the rejection of their claimed invention over Littman in view of Diaz/Fujii or Fusion in view of Diaz. Further, Folden does not evidence a reasonable expectation of success. Thus, the claims are patentable over the cited documents.

4. Claim 27 was rejected under Section 103(a) as allegedly unpatentable over Littman in view of Diaz/Fujii or Fusion in view of Diaz (either of the previous rejections), and further in view of Suzuki et al. (U.S. Patent 2004/0031756). Applicant traverses because the additional citation of Suzuki does not correct the deficiencies discussed above with respect to the rejection of their claimed invention over Littman in view of Diaz/Fujii or Fusion in view of Diaz. Further, Suzuki does not evidence a reasonable expectation of success. Thus, the claims are patentable over the cited documents.

Withdrawal of the Section 103 rejections is requested because the claims would not have been obvious to one of ordinary skill in the art when this invention was made.

#### *Conclusion*

Having fully responded to the pending Office Action, Applicant submits that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if additional information is required.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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